



DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 25 1999

Food and Drug Administration  
Rockville MD 20857

2009 OCT 25 2:11:19

The Honorable Richard W. Pombo  
Chairman, Subcommittee on Livestock and Horticulture  
Committee on Agriculture  
House of Representatives  
Washington, D.C. 20515-6003

Dear Mr. Chairman:

Thank you for your letter of September 24, 1999, also signed by eleven of your colleagues concerning the Food and Drug Administration's (FDA or the Agency) proposed rule on refrigeration and safe handling labeling of shell eggs which was published in the Federal Register of July 6, 1999.

You and your colleagues express concern that while an educational message is appropriate, the labeling options proposed by FDA are inappropriately alarmist as shown by a study commissioned by the American Egg Board. You support alternative wording proposed by egg producers.

We appreciate your thoughtful comments on our proposed rule. Although the comment period for this regulatory proposal closed on September 20, 1999, your comments will be forwarded to the docket for this issue. The Agency does try, as time and resources permit, to accommodate comments received after the comment period.

Please contact us if we may be of further assistance in this matter. A similar letter has been sent to the co-signers of your letter.

Sincerely,

Melinda K. Plaisier  
Associate Commissioner  
for Legislation

cc: Dockets Management Branch  
(Docket No. 98N-1230)

96P-0418

C 762/ANS

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF THE SECRETARY  
EXECUTIVE SECRETARIAT

SECRETARY'S CORRESPONDENCE

From: CONGRESSIONAL, DE(12)

OS#: 09/30/1999 0012

On Behalf Of:

DOL: 09/24/1999

Type: Congressional

Dt Inc Rec'd: 09/30/1999

Code: Correspondence

Org: U. S. HOUSE OF REPRESENTATIVES

Add: WASHINGTON, DC

Due in OS/ES:10/15/1999

Subject:

12 MEMBERS OF THE HOUSE, INCLUDING RICHARD POMBO, COLLIN PETERSON, JOHN MCHUGH, CHARLES CANADY, NATHAN DEAL AND OTHERS, RE FDA PROPOSED RULE WITH RESPECT TO THE REFRIGERATION AND LABELING OF SHELL EGGS. SEEKS SERIOUS CONSIDERATION OF COMMENTS AND WOULD LIKE TO BE ADVISED OF FDA'S DECISION.

Assigned to: FDA

On: 09/30/1999

Action: SEC SIG

ES Dep: White

PC: Friebert

Info Copies: CCC ASL AMB OGC ASP PHS CDC SEC ESS WHITE FRIEBERT

Interim (Y/N):

Interim Signed:

Reply Rec'd in OS/ES:

Final Signed:

OPDIV/STAFFDIV ROUTING SECTION  
(Recipient should sign & date when received)

SENT TO	DATE	TIME	RECEIVED BY	DATE	TIME
			FDA/OL	10/4/99	

Comment:

File Index: PO 4-6

Scheduling ID:

CCC: OLH

No. 99-6347

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**U.S. House of Representatives**  
**Committee on Agriculture**  
**Subcommittee on Livestock and Horticulture**  
**Room 1301, Longworth House Office Building**  
**Washington, DC 20515**

September 24, 1999

Honorable Donna Shalala  
Secretary of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Madam Secretary:

As members of Congress interested in the well-being of consumers and the future viability of the U.S. egg industry, we submit this letter as a comment on the Food and Drug Administration's proposed rule of July 6, 1999, amending 21 CFR Parts 16, 101, and 115 with respect to the refrigeration and labeling of shell eggs. We ask that this letter be made part of the official record with respect to Docket Nos. 98N-1230, 96P-0418, and 97P-0197.

We believe the concept of an educational message on egg cartons instructing consumers on their role in insuring food safety is appropriate. In fact, Congress amended the Egg Products Inspection Act, the principal statute governing the handling and inspection of eggs, to require both the refrigeration of shell eggs during transportation and storage and a label with the words "Keep Refrigerated."

Unfortunately, the label wording proposed July 6 by FDA is inappropriately alarmist and will not be effective at encouraging the behavioral changes that are its stated goal. Instead, the label runs a high risk of reducing consumer demand while not effecting the changes in food handling practices that will help assure food safety.

It is appropriate for egg producers, processors and government to work in partnership in order to convey safe handling information to consumers and workers in food-service industries. With safe preparation, the already-low risk of contracting salmonellosis from eggs is effectively eliminated. In this way, a safe product (only one in 20,000 eggs is contaminated with *Salmonella enteritidis*) can be made even safer.

We believe that each of the proposed label options contain wording that is unnecessarily alarmist. Research commissioned by the American Egg Board and involving personal interviews with 300 adult consumers tends to substantiate our concern. The consumers were shown the proposed FDA label and three alternatives, each involving briefer text as well as illustrative icons. The surveys found that –

No. 89-6347

- The majority of respondents saw the FDA label as a warning rather than a message to promote specific actions such as refrigeration. Of these respondents, most viewed the FDA label as either (1) a message about bacteria or (2) a warning that eggs can be harmful.
- The alternative labels alerted consumers without alarming them and promoted specific consumer actions.
- Almost three times as many consumers said that the message from one of the alternative labels was "refrigerate" as gave this response for the FDA label. Consumers saw refrigeration as a primary message in each of the alternative labels.
- Similarly, the alternative labels got higher marks for encouraging "cleanliness" and conveying information on "how to cook/take care of eggs" than did the FDA label.
- A much larger portion of the consumers saw the main point of one of the alternative labels as safety (36% vs. 17% for the FDA label).

We understand that you will have access to this and other research in the public comments filed by the United Egg Producers. The government should act on sound information and choose label wording that will best achieve its goal, not merely convey the most strident message.

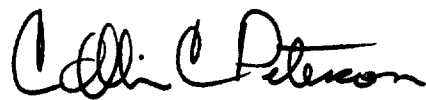
As members of Congress, we support alternative wording proposed by egg producers and urge FDA to adopt it. The wording builds on consumer-tested messages and the successful FightBAC campaign developed jointly by government and industry.

Your serious consideration of these comments will be greatly appreciated. Please advise us of your and FDA's decision.

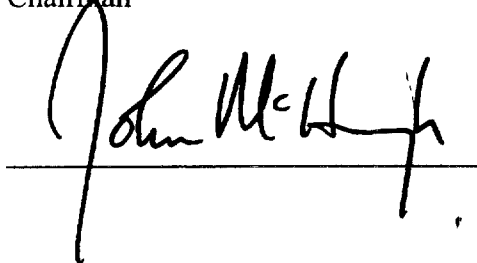
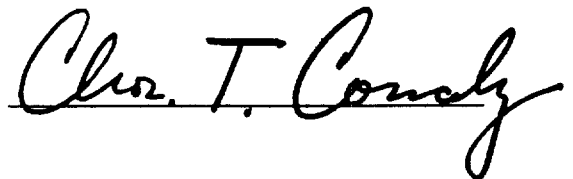
Sincerely,

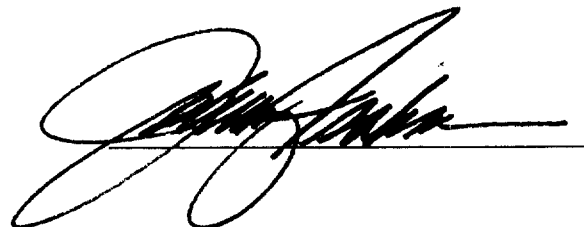


RICHARD W. POMBO  
Chairman



COLLIN PETERSON  
Ranking Member



Thompson

Joe Beyer

Virgil Gooder

George R. Ketchum

Asa Hatchman

Charles

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Signature Page

The Honorable Richard Pombo  
Chairman

The Honorable Collin Peterson  
Ranking Member

The Honorable John McHugh

The Honorable Charles Canady

The Honorable Nathan Deal

The Honorable Johnny Isakson

The Honorable Thomas Reynolds

The Honorable Steve Buyer

The Honorable Virgil Goode

The Honorable George Nethercutt

The Honorable Asa Hutchinson

The Honorable Gary Condit

09-30-99-0012

CROSS FILE SHEET

File Number: 98N-1230/ C 762 / ANS

See File Number: 97P-0197/ C 763 / ANS  
96P-0418/ C 762 / ANS